Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient PPS – to be used for tracking purposes

1. Applicant Name: ***Medtronic Sofamor Danek, Inc.*** Date: 10/24/02
2. Manufacturer Name: ***Medtronic Sofamor Danek***
3. Contact Name: ***Robert C. Peterson***
4. Address: ***1800 Pyramid Place Memphis, TN 38132***
5. Telephone Number: ***(800)876-3133 or (901)344-1573***
6. Email Address: **rpeterson@sofamordanek.com**
7. Trade Brand of Technology: ***INFUSE™ Bone Graft***
8. Brief Description of Service or Device:

   INFUSE™ Bone Graft/LT-CAGE Lumbar Tapered Fusion Device consists of two components containing three parts – a tapered metallic spinal fusion cage, a recombinant human bone morphogenetic protein and a carrier/scaffold, absorbable collagen sponge (ACS), for the bone morphogenetic protein and resulting bone. The INFUSE™ Bone Graft component induces new bone tissue at the site of implantation. The INFUSE™ Bone Graft component is inserted into the LT-CAGE Lumbar Tapered Fusion Device component to form the complete device. rhBMP-2 is the active agent in the INFUSE™ Bone Graft component.

New Criteria

9. Date of FDA approval for the device or service: ***July 2, 2002***
10. Was the service or technology considered under FDA priority review? ***Yes***
11. Does the service or technology have an ICD-9-CM code or is one pending? If yes, please specify. ***84.52 – Insertion of recombinant human bone morphogenetic protein***.
12. Does the service or technology have a HCPCS code associated with it? If yes, please specify. ***N/A – see question 14.***

13. If the technology is a device, is there an IDE number assigned to the device? If yes, please specify. ***When the device was in clinical trials, the IDE number was G960065. The PMA number is P000058.***

14. Have you submitted an outpatient application for pass-through payments under the Medicare outpatient prospective payment system? If so, when? Have you been approved? If yes, when was your approval? ***Not applicable as spine fusion is not eligible for reimbursement under HOPPS as it is an in-patient only procedure.***

Cost Criteria

15. Affected diagnosis-related groups (DRGs): ***496, 497, 498***

16. What is the anticipated volume of this technology (by DRG)? ***Please refer to the FY03 Estimated New Tech DRG Additional Payments PowerPoint Handout attached to the application.***

17. Weighted standard deviation threshold in affected DRGs: ***Please refer to Exhibit 2.***

18. What is the anticipated average standard charge per case involving this new technology? ***Please refer to Exhibit 2.***

19. What is the estimated cost per case for the service or technology? ***For DRG 498, the estimated cost per case is $20,843.***

20. Number of cases/patients, distinguishing between Medicare and non-Medicare: ***For FY2003E: 25% BMP Utilization: 2,329 Medicare cases, 13,960 Non-Medicare; 50% Utilization: 4,659 Medicare, 27,919 Non-Medicare***

21. Average dosage/number of units and estimated costs for sub-populations: ***1.5 ml/mg per fusion level***

Clinical Improvement

22. Please provide a short synopsis of the following clinical issues added to the new technology. Use the regular application to submit full details.

a. Briefly describe how the new service or technology represents a substantial clinical improvement over existing services or technologies:

INFUSE™ Bone Graft substantially improves the induction of new bone when implanted for lumbar interbody fusion and eliminates the necessity to harvest autogenous bone from the iliac crest. In the past when there was an absence of a better alternative, it was necessary to do harm, harvest iliac crest bone, for the greater good. With the availability now of a safe and efficacious replacement such as INFUSE™ Bone Graft, there may well be a medical imperative to obviate the need for a second surgery associated with bone graft harvesting and the associated morbidity.

Clinically, INFUSE™ Bone Graft is more appropriate to use and has been proven more effective in its use than autogenous iliac crest bone graft, when either is placed in the LT-CAGE™ Lumbar Tapered Fusion Device for anterior lumbar interbody fusion. Use of INFUSE™ Bone Graft instead of autogenous iliac crest bone graft:

- ***Obviates iliac crest bone graft donor site morbidity.***
- ***Reduces operative time, blood loss and hospitalization.***
- ***Results in greater fusion success.***
- ***We found that the Oswestry Low Back Pain Disability score and SF-36 Physical Component and Pain Index scores were consistently 10% better in the INFUSE™ Bone Graft group than the autogenous iliac bone graft group.***
- ***Enables earlier return to work.***

b. Briefly describe relevant clinical trial(s), including dates and findings: ***please reference the following:***

Boden SD, Zdeblick TA, Sandhu HS, Heim SE. The use of rhBMP-2 in interbody fusion cages. Definitive evidence of osteoinduction in humans: a preliminary report. Spine 2000;25:376-381.

Burkus JK, Gornet MF, Dickman C, Zdeblick T, Anterior Lumbar Interbody Fusion Using rhBMP-2 with Tapered Interbody Cages. J Spinal Disord 2002;15:337-349.

c. List of published peer-review articles relevant to the new service or technology:

Ackerman SJ, Mafilios MS, Polly DW Jr. Economic evaluation of bone morphogenetic protein versus autogenous bone graft in single-level anterior lumbar interbody fusion: an evidence-based modeling approach. Spine 2002:27:S94-S99.

Arrington ED, Smith WJ, Chambers HG, et al. Complications of iliac crest bone graft harvesting. Clin Orthop 1996;329:300-9.

Banwart JC, Asher MA, Hassanein RS. Iliac crest bone graft harvest donor site morbidity: A statistical evaluation. Spine 1995;20:1055-60.

Boden SD. Biology of lumbar spine fusion and use of bone graft substitutes: present, future, and next generation. Tissue Engineer 2000;6:383-399.

Boden SD, Martin GJ Jr, Horton WC, et al. Laparoscopic anterior spinal arthrodesis with rhBMP-2 in a titanium interbody threaded cage. J Spinal Disord 1998;11:95-100.

Boden SD, Zdeblick TA, Sandhu HS, Heim SE. The use of rhBMP-2 in interbody fusion cages. Definitive evidence of osteoinduction in humans: a preliminary report. Spine 2000;25:376-381.

Burkus JK, Gornet MF, Dickman C, Zdeblick T, Anterior Lumbar Interbody Fusion Using rhBMP-2 with Tapered Interbody Cages. J Spinal Disord 2002;15:337-349.

Goulet JA, Senunas LE, DeSilva GL, Greenfield MLVH. Autogenous iliac crest bone graft: complications and functional assessment. Clin Orthop 1997; 339:76-81.

Kalk WW, Raghoebar GM, Jansma J, et al. Morbidity from iliac crest bone harvesting. J Oral Maxillofac Surg 1996; 54:1424-9.

Mirovsky Y, Neuwirth MG. Comparison between the outer table and intracortical methods of obtaining autogenous bone graft from the iliac crest. Spine 2000; 25:1722-1725.

Sawin PD, Traynelis VC, Menezes AH. A comparative analysis of fusion rates and donor-site morbidity for autogenous rib and iliac crest bone grafts in posterior cervical fusions. J Neurosurg 1998; 88:255-65.

Younger EM, Chapman MW. Morbidity at bone graft donor sites. J Orthop Trauma 1989;3:192-195.

Exhibit 1: Summary of process for creating analytic data file

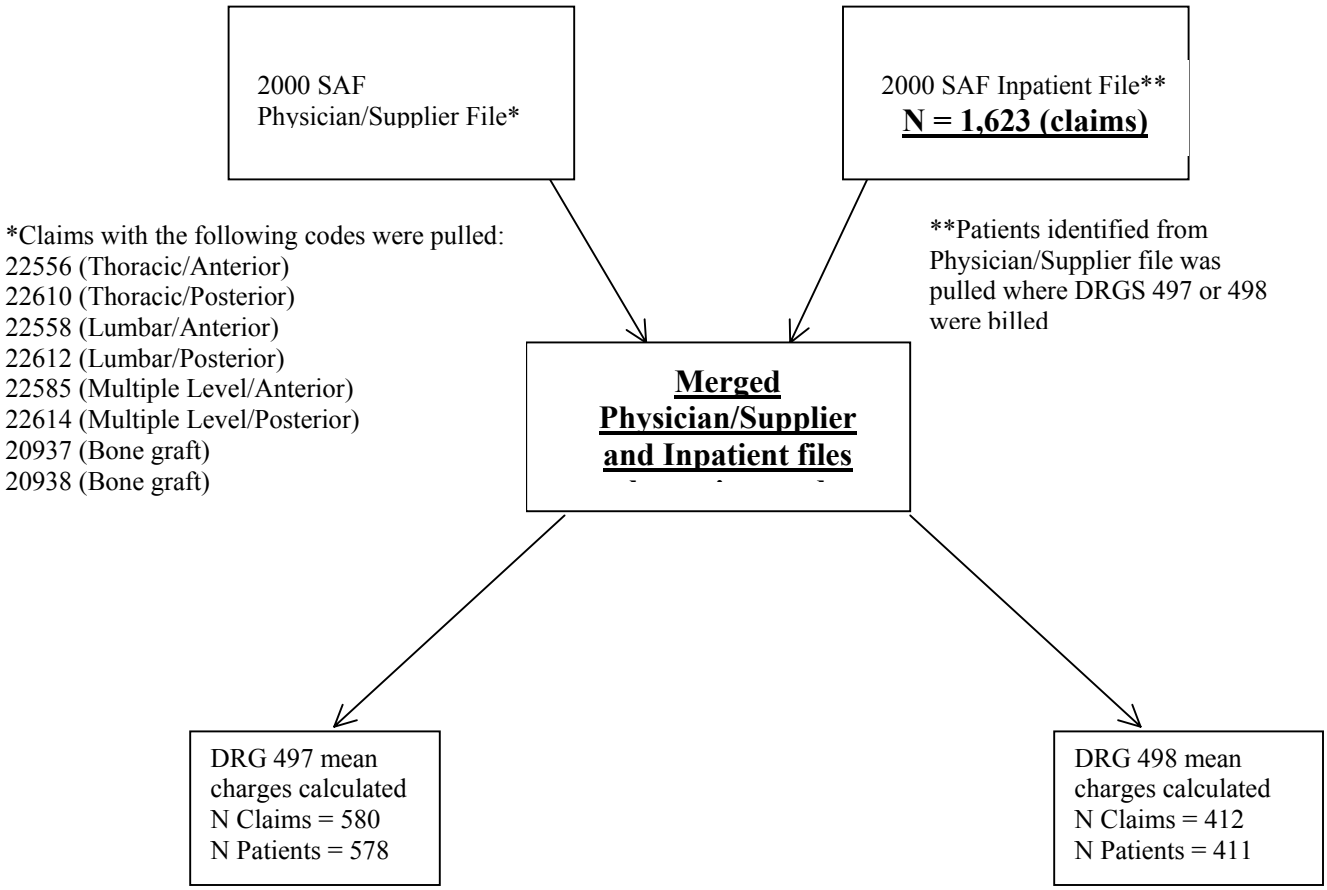

Exhibit 2: Summary of mean standardized charges by DRG for spinal fusion cases

Lumbar Procedures**

DRG	Number of Levels	Patients	Mean Total Standardized Charges (FY 00 Observed)	SD Total Standardized Charges (FY 00 Observed)	INFUSE Average Charges*	INFUSE Charges > Mean Standardized Charges	INFUSE Exceeds SD
497	1) Single	265	$29,763	$15,883.43	$41,321	11,558	NO
	2) Two Level	211	$35,085	$20,506.99	$59,101	24,016	YES
	3) Three or more Levels	76	$40,955	$23,659.60	$76,881	35,926	YES
498	1) Single	195	$22,556	$14,379.44	$37,200	14,644	YES
	2) Two Level	173	$26,039	$13,227.69	$54,980	28,941	YES
	3) Three or more Levels	32	$33,185	$16,392.03	$72,760	39,575	YES

*Derived from New Tech DRG Application Supplemental Data
**Lumbar/Thoracic combined grouped into Lumbar Procedures